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(collectively, “Mylan”), and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively “Teva”). Plaintiffs, patent-holders and drug-makers, sued Defendants, generic drug manufacturers, for alleged infringements of patents on the chemical compound darunavir, used in the manufacture of Plaintiffs’ product, Prezista, arising out of Defendants’ filing of Abbreviated New Drug Applications (“ANDAs”) seeking approval to sell generic versions of Prezista. Amended Complaint, ECF No. 267 ¶ 1. The facts of the case are presented thoroughly in the Court’s August 14, 2014 opinion finding patent infringement by the Defendants and granting Plaintiffs’ request for a permanent injunction barring Defendants from manufacturing, importing, using or selling their ANDA products in the United States, ECF No. 943, and are incorporated here by reference.

In the opinion and accompanying order, ECF No. 944, the Court held in part that the sale of darunavir tablets described in Lupin’s ANDA 202073 would infringe claim 1 of U.S. Patent No. 7,126,015 (the ‘015 Patent), and claim 4 of U.S. Patent No. 7,700,645 (the ‘645 Patent), which are held by Plaintiffs, *id.* at 1, 2, and enjoined Lupin from “using, selling, or offering for sale in the United States, or importing into the United States, the [ANDA 202073 product] or any darunavir product that includes” the components protected by the ‘015 Patent or the ‘645 Patent. *Id.*

Defendants Mylan and Lupin filed a motion to amend the August 14, 2014 injunctive order on August 19, 2014, ECF No. 947, which the Court denied on October 7, 2014. ECF No. 2012. Defendants Mylan and Lupin separately appealed the August 14, 2014 judgment “and all underlying adverse opinions, orders, decisions, and rulings subsumed within said Judgment and/or made prior to entry of Judgment in this action, and/or relating to the scope of any relief award pursuant to said Judgment” on September 12, 2014. Lupin Notice of Appeal, ECF No. 983 at 2;

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Mylan Notice of Appeal, ECF No. 984 at 2. Lupin's appeal is currently pending before the Federal Circuit. *Janssen Products, L.P. v. Lupin Limited*, No. 14-1842 (Fed. Cir. 2014).

On November 9, 2015, after Janssen and Mylan completed briefing but before the Federal Circuit heard oral argument on Mylan's appeal, Janssen and Mylan executed a settlement agreement and license agreement resolving Janssen's claims against Mylan. Mylan Joint Mot. Indicative Ruling, ECF No. 1063 at 1. On December 11, 2015, this Court issued an indicative ruling under Fed. R. Civ. P. 62.1 that, if the case were remanded from the Federal Circuit, the Court would modify the terms of its August 14, 2014 order to incorporate the terms of the Janssen-Mylan settlement agreement and license agreement. ECF No. 1065. The Federal Circuit remanded Mylan's appeal on January 21, 2016, ECF No. 1067, and this Court issued an order modifying the terms of its August 14, 2014 order with respect to Mylan on March 15, 2016. ECF No. 1069.

Janssen and Lupin now inform the Court that, on May 26, 2016, after Janssen and Lupin completed briefing but before the Federal Circuit heard oral argument on Lupin's appeal, Janssen and Lupin executed a settlement agreement and license agreement resolving Janssen's claims against Lupin. Lupin Joint Mot. Indicative Ruling, ECF No. 1072 at 1. Under the agreement, Janssen will permit Lupin to market ANDA 202073 products at a specified date before the expiration of the '015 and '645 Patents. *Id.* at 1. The August 14, 2014 injunctive order currently bars Lupin from manufacturing or selling these products before the expiration of the Patents and the end of any "associated pediatric exclusivity period" for the '645 Patent. *Id.*

At the parties' request, the Federal Circuit granted a stay of further appellate proceedings pending the completion of Janssen and Lupin's settlement. *Id.* at 2; *Janssen*, No. 14-1842, ECF No. 107. On June 7, 2016, Janssen and Lupin filed a motion in this Court under Fed. R. Civ. P. 62.1 for an indicative ruling that, if the case were remanded, the Court would modify the August

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14, 2014 injunctive order to allow Lupin to manufacture and sell ANDA products during the term of the '015 and '645 Patents as permitted in the settlement agreement. ECF No. 1072.

The Court now considers whether (a) it may issue an indicative ruling under Rule 62.1 and (b) whether modification of the August 14, 2014 injunction is warranted under Rule 60(b).

STANDARD OF REVIEW

“Generally, a notice of appeal divests the District Court of jurisdiction ‘over those aspects of the case involved in the appeal.’” *Kull v. Kutztown Univ. of Pa.*, 543 Fed App’x 244, 248 (3d Cir. 2013) (quoting *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982)). Under Fed. R. Civ. P. 62.1, if a party files a motion “that the court lacks authority to grant because of an appeal that has been docketed and is pending, the court may: (1) defer considering the motion; (2) deny the motion; or (3) state either that it would grant the motion if the court of appeals remands for that purpose or that the motion raises a substantial issue.” Fed. R. Civ. P. 62.1(a). According to the Advisory Committee Notes from Rule 62.1’s adoption in 2009, this rule codifies “the practice that most courts follow when a party makes a Rule 60(b) motion to vacate a judgment that is pending on appeal. After an appeal has been docketed and while it is pending, the district court cannot grant a Rule 60(b) motion without a remand,” but it can “state that it would grant the motion if the court of appeals remands for that purpose.” Fed. R. Civ. P. 62.1 2009 Advisory Committee Notes; *see also Ray v. Pinnacle Health Hospitals, Inc.*, 416 Fed App’x 157, 161 n.3 (3d Cir. 2010) (discussing indicative rulings under Rule 62.1 and noting that “Rule 62.1 was designed to adopt the practice most trial courts follow when a party makes a Rule 60(b) motion.”). If the court issues an indicative ruling stating that it would grant the motion, the “movant must promptly notify the circuit clerk under Fed. R. App. P. 12.1.” Fed. R. Civ. P.

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62.1(b). “The district court may decide the motion if the court of appeals remands for that purpose.” Fed. R. Civ. P. 62.1(c).

Fed. R. Civ. P. 60(b) allows a court to provide relief from a judgment or order when, among other things, “applying the judgment order prospectively is no longer equitable” (subsection (b)(5)), or “for any other reason that justifies relief” (subsection (b)(6)). The Court’s power to grant relief under this rule is narrow. “Due to the overriding interest in the finality and repose of judgments, a Rule 60(b) motion is considered extraordinary relief which should be granted only where extraordinary justifying circumstances are present.” *Katz v. Twp. of Westfall*, 287 Fed App’x 985, 988 (3d Cir. 2008) (quotations and citations omitted).

“[I]t is appropriate to grant a Rule 60(b)(5) motion when the party seeking relief from an injunction or consent decree can show a ‘significant change either in factual conditions or in law.’” *Agostini v. Felton*, 521 U.S. 203, 215 (1997) (quoting *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 384 (1992)). If the movant can demonstrate this significant change in factual conditions or law, the Court should “consider whether the proposed modification is suitably tailored to the changed circumstances.” *Rufo*, 502 U.S. at 383.

DISCUSSION

I. An indicative ruling is warranted under Rule 62.1

The parties jointly move for a Rule 60(b) modification of this Court’s August 14, 2014 injunctive order against Lupin. ECF No. 944. As discussed, the Court does not have jurisdiction to modify the order because Lupin’s appeal of the August 14, 2014 order is pending before the Federal Circuit. *Kull*, 543 Fed App’x at 248. Under Rule 62.1, the Court may issue an “indicative ruling” stating “that it would grant the motion if the court of appeals remands for that purpose.”

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Fed. R. Civ. P. 62.1(a). As the Court will discuss, it will grant the Rule 60(b) motion if the Federal Circuit remands for that purpose.

II. The Court would grant the parties' joint Rule 60(b) motion to modify the injunctive order.

The parties seek a limited modification of the Court's August 14, 2014 order enjoining Lupin from manufacturing and selling ANDA products. The proposed order does not modify the Court's earlier findings of fact or conclusions of law, ECF No. 943, nor does it modify the Court's judgment against Defendant Teva.¹ Proposed Order Modifying Judgment, ECF No. 1072 Ex. A. Instead of holding that Lupin's production of the darunavir tablets described in ANDA 202073 would infringe claim 1 of the '015 Patent and/or claim 4 of the '645 Patent and enjoining Lupin from producing, using, selling, or importing the tablets at any time before the Patents' expiration, the proposed modified order states that production, importation, use, sale, or offer for sale in the United States would infringe both Patents "absent a license from Plaintiffs" and enjoins Lupin from producing the tablets "before such date provided under the Settlement Agreement and License Agreement between Lupin and Plaintiffs." *Id.* at 1-2.

Modification of the August 14, 2014 injunctive order is appropriate under Rule 60(b)(5) and 60(b)(6) because applying the judgment prospectively "is no longer equitable." Fed. R. Civ. P. 60(b)(5). There has been a "significant change . . . in factual conditions," *Agostini v. Felton*, 521 U.S. at 215, namely that Janssen and Lupin have settled and that Janssen has agreed to allow Lupin to sell darunavir tablets at a certain future date. Given the Third Circuit's strong policy "in favor of voluntarily settlement agreements," *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 594 (3d

¹ As discussed, the Court modified its judgment against Defendant Mylan on March 15, 2016 to accommodate a similar settlement and license agreement between Janssen and Mylan. ECF No. 1069.

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Cir. 2010), it would be inequitable for the Court to refuse to modify a judgment preventing the parties from carrying out this settlement. *See also Tommy Hilfiger Licensing, Inc. v. Costco Companies, Inc.*, 2002 WL 31654958 (S.D.N.Y. Nov. 25, 2002) (granting motion for indicative ruling vacating judgment under Rule 60(b)(6) because parties settled while matter was on appeal to Second Circuit); *but see Vertex Surgical, Inc. v. Paradigm Biodevices, Inc.*, 648 F. Supp. 2d 226, 239 (D. Mass. 2009) (discussing at length denial of parties' joint motion for relief from judgment because there is "nothing exceptional" in a "plain vanilla settlement" requiring Rule 60(b)(6) relief, and explaining that "a judicial decision rendered with finality should be addressed on the merits and then discarded only if unpersuasive on the merits.").

The proposed modified order is appropriate here because it is "suitably tailored to the changed circumstances." *Rufo*, 502 U.S. at 383. The proposed order leaves intact the Court's findings of fact and law and the injunctive relief ordered against the remaining Defendants. Additionally, Lupin would still be liable for patent infringement if it produced or sold darunavir tablets before the date specified in the settlement agreement or otherwise in violation of the "license from Plaintiffs." ECF No. 1072 Ex. A at 1-2. The modified judgment does not "discard" the Court previous decision, *Vertex*, 648 F. Supp. 2d at 239, but simply allows the settling parties to comply with the terms of their settlement agreement.

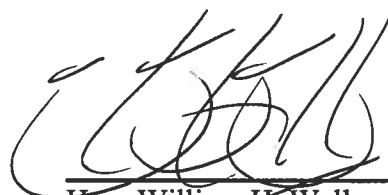
CONCLUSION AND ORDER

The Court finds that the jointly requested 60(b) relief is warranted, ECF No. 1072, but lacks jurisdiction to modify the August 14, 2014 opinion and order, ECF No. 933, 934. For this reason, the Court advises the Federal Circuit that, if the case is remanded for this purpose, the Court will issue the proposed order modifying judgment with respect to Lupin, ECF No. 1072 Ex. A, allowing the settling parties to comply with the terms of their settlement agreement. Janssen

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and Lupin are hereby ordered to notify the circuit clerk of this indicative ruling under Fed. R. Civ. P. 62.1(b).

DATE: 15 June 2016



Hon. William H. Walls
United States Senior District Judge